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EXAMINER

BUI, KIM T

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/524,826

Applicant(s)

TANG ET AL.

Examiner

Kim T. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Recent Statutory Changes to 35 U.S.C. § 102(e)

On November 2, 2002, President Bush signed the 21st Century Department of Justice Appropriations Authorization Act (H.R. 2215) (Pub. L. 107-273, 116 Stat. 1758 (2002)), which further amended 35 U.S.C. § 102(e), as revised by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)). The revised provisions in 35 U.S.C. § 102(e) are completely retroactive and effective immediately for all applications being examined or patents being reexamined. Until all of the Office's automated systems are updated to reflect the revised statute, citation to the revised statute in Office actions is provided by this attachment. This attachment also substitutes for any citation of the text of 35 U.S.C. § 102(e), if made, in the attached Office action.

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 prior to the amendment by the AIPA that forms the basis for the rejections under this section made in the attached Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

For more information on revised 35 U.S.C. § 102(e) visit the USPTO website at www.uspto.gov or call the Office of Patent Legal Administration at (703) 305-1622.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) In claim 1, "the text on the clinical guideline" on line 4 and "the information in the active guideline tag" on line 13, lack clear antecedent basis. Also, it is unclear if "clinical guidelines", "active guidelines" and "accessed clinical guideline" on lines 2 and 12 refer to the same thing. Furthermore, the conditional statement " If the user" on line 12 renders the claimed invention unclear and indefinite, it is unclear if the applicant intends to claim a method consisting of steps a and b if the user does not accept the guideline.

(B) In claim 6, "the text of a hyperlink" on line 7, "the acceptance of the recommendation" on line 8, and "the patient" on line 11 lack clear antecedent basis.

(C) In claim 9, " the active guidelines" on line 1, lacks clear antecedent basis.

(D) In claim 10, " the recommendation" on line 9, lacks clear antecedent basis.

(E) In claim 11, "the selected web page" and "the accepted guideline" on lines 3-4 and line 5, lack clear antecedent basis.

(F) In claim 12 "the action item" on line 1, lacks clear antecedent basis.

(G) In claim 13, "the action item" on line 1, lacks clear antecedent basis

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(H) Claims 7-9 and 12,13 are indefinite because they further limit a method that is not recited in the independent claims 6 and 10.

(I) Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: "the viewer and the interpreter".

(J) Dependent claims 11-13 incorporate the deficiency of claim 10 through dependency, and are therefore rejected.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 6-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The statutory status of the instant claims under Section 101 will be analyzed with guidance from MPEP Section 2106.

(A) Claim 6 directed to an active guideline server for use at a healthcare institution, the server including a computer readable storage device programmed to store data set, and recites two components of the data set in the body of the claim. Whether the claim is recited to be "guideline server including a computer readable storage device programmed to store data set" will not be dispositive of the statutory of the claim under Section 101. In particular, the claim does not define any structural and functional

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interrelationships between the recited "text" and "set of active guideline tags" and other elements of a computer, which permit the functionality of the data set to be realized.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)

The policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional descriptive material. The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture. As such, the claimed "data set " is considered to be "non-statutory non-functional descriptive material".

In addition, for a claimed invention to be statutory, it must produce a useful, concrete, and tangible result. In the present case, claims 6-9 recite a mere

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arrangement of text and tags in a data set and therefore produce no useful, concrete or tangible result.

(B) Dependent claims 7-9 further define the action item and active guidelines. The further limitations do not provide the practical application of the data set. The claims are rejected for the same reasons given above in the rejection of claim 1.

(C) Claim 10 recites active guideline component "including "active guidelines viewer" and "active guidelines interpreter" disclosed as software component. See specification page 5, lines 13-24. The recited software component is not a process. Claim 10 fails to define any structural or functional interrelationships between the software and other computer elements to permit the software's functionality to be realized.

For reasons given above, the claimed "active guideline viewer" and "active guideline interpreter" appear merely to be software programs, that are non-statutory functional descriptive material.

In addition, for a claimed invention to be statutory, it must produce a useful, concrete, and tangible result. In the present case, claim 10 recites useful and concrete (i.e. capable of displaying and repeatable) but not tangible result for there is no provision to permit the software's functionality to be realized.

(D) Dependent claims 11-13 further define the action item and active guidelines, these limitations do not further provide any execution of the software program. The claims are rejected for the same reasons given above in the rejection of claim 10.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1,3,4,5,6,8,9,10,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (US 6149585).

(A) As per claim 1, Gray discloses a healthcare system having guideline server for maintaining diagnostic enhancement application including:

- a. guideline server for maintaining clinical guideline text and associated tags (see col.2, lines 41-42, col.2, line 65, col.5, lines 25);
- b. client or user terminal including web browser for viewing guideline information and hyperlink (see col.2 ,lines 42-43, col.6,lines 50-68, Fig.19);
- c. the user click on the hyperlink to initiate his selection and upon his acceptance, an order or diagnosis test is posted to be performed by a selected radiologist or other specialist (see col.8, lines 23-26, fig. 19, col. 9, lines 43-55, col.10, 53-61).

This meets the guideline server, the user station, the web browser, the displayed clinical guideline, and the user's acceptance of recommendation by invoking hyperlink in claims 1,6,10. Gray does not explicitly disclose the tag and the interpreter to process to tag to present the hyperlink, but lines 50-53 and lines 61-68, col.2, Fig. 21 of Gray teaches that the client receive the HTML documents from the server to present recommendation guideline information including hyperlink to the user for selection. It is

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apparent that HTML suggested by Gray requires embedded tag to instruct the browser to display the text or image in specified format including hyperlink as shown in the drawings, particularly fig.19. With the HTML at the client terminal, one with ordinary skill in the art at the time of the invention would have found it obvious to incorporate appropriate translator or interpreter to present hyperlink with the motivation for facilitating the method for assisting physician to make better decision on treatment plan by proving faster access to needed information as well as to smoothen navigation through the presented information.

(B) Claim 6 recites data set having text and associated tag including the text of the hyperlink which can be displayed for the user to identify the acceptance of recommendation and information that can be transmitted to the patient record system for an action item to be initiated. This is disclosed in Gray as discussed in the above rejection applied to claim 1. The text and tags are suggested by the HTML as discussed above. Claim 6 is rejected for the same reasons given above in the rejection of claim 1.

(C) Claim 10 recites the active guideline component having a viewer and an interpreter for the display of clinical guideline and the user acceptance of recommendation. This is disclosed in Gray as discussed in the rejection of claim 1. Gray does not explicitly recite the interpreter as recited in claim 10. The reference, however, teaches the HTML and the displayed hyperlink with text as discussed in the rejection of claim 1. One with ordinary skill in the art at the time of the invention would have found it obvious to incorporate appropriate translator or interpreter to present hyperlink with the motivation of facilitating the method for assisting physician to make better decision on

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treatment plan by providing faster access to needed information as well as to smoothen navigation through the presented information.

(D) As per claims 3,8, Gray discloses a procedure to be performed on col. 6, lines 50-60.

(E) As per claims 4, 5, Gray teaches network environment including the Internet (HTTP network) on col.2, 41-43, col.3, lines 24-41.

(F) As per claim 9, Gray discloses HTML document on col. 2, line 65.

(G) As per claim 11, it is noted that Gray teaches that the clients and the server are communicated via the Internet (see col. 2, lines 38-52). The user also request for additional references through hypertext links (see col.7, 43-46), which apparently would include address locator or URL to allow a path to locations or addresses of the requested references.

7. Claims 2,7,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (US 6149585) as applied to claims 1,6,10 above, and further in view of DeLaHueraga (US 6408330).

(A) As per claims 2,7,12.Gray does not disclose the issuing of prescription. This, however, is disclosed in DeLaHueraga . DeLaHueraga discloses a physician assistance healthcare apparatus including a link to pharmacy server, upon verification of an ordered prescription, dispensation is approved (see col.53, lines 1-19, Fig. 13C, Fig. 30). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the prescription feature disclosed in DeLaHueraga into the system of Gray with the motivation for providing the physician with a standard and

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effective healthcare assistance system since it is commonly known for a physician to give prescription besides medical tests to effectively treat a patient.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim T. Bui whose telephone number is 703-305-5874.

The examiner can normally be reached on Monday-Friday from 8:30A.M. to 5:00P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are 703- 305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3900.

November 22, 2002


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600